

PREGNOLIA PROBE

Quick Reference Guide

Short Instructions for Use
P/N 100057 - D

2019-01-16

Other languages available at
www.pregnolia.com/instructions
Latest version available at
www.pregnolia.com/instructions

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Use Environment

The Pregnolia System is designed for use in a gynaecological examination room equipped for speculum-based vaginal examinations. In addition, noise levels should be moderate so as not to obscure the audio signals emitted by the system. The system is to be used with the aid of a speculum and, if necessary, an external illumination source. Furthermore, the use of standard medical accessories is necessary, such as gloves to handle the *sterile probe* and swabs and saline solution to clear the cervix of excessive mucus. The patient shall be seated and positioned in a manner consistent with routine practice for speculum-based vaginal examination.

Contraindications

The Pregnolia System has been designed to minimise any foreseeable risks when correctly used on healthy women. However, the user must assess the appropriateness of using the system on a case by case basis, and evaluate the overall risk posed by its usage to the woman or, if applicable, to the foetus. The measurement must be conducted on native cervical tissue. The use of the Pregnolia System is contraindicated in the following situations: severe vaginal bleeding; light bleeding (if the bleeding can be stopped, it is no longer a contraindication); *placenta praevia totalis* with haemorrhage (irrespective of severity); lack of consent for vaginal examination by the patient; rupture of membranes before 34 weeks and without contractions; cervical dilation; cervical carcinoma; known HIV; visible, symptomatic cervical or vaginal infections (this excludes treated, asymptomatic infections); Müllerian anomalies with two cervixes; *if one of the following conditions is present on the cervix at the 12 o'clock position*: Nabothian cyst, cervical myomas, cervical condylomas, squamous intraepithelial lesion, conisation / LEEP / LLETZ, cervical endometriosis, cervical tears, cervical dysplasia, large ectopy - for which it

! Important points

- **Do not completely open** the *probe sterile pouch* before connecting the *filters*.
- **Do not touch** the *probe* without gloves.
- **Do not touch** the *probe tip*.
- Start the pump **before** approaching the cervix.
- Measure on the anterior lip of the cervix at 12 o'clock position.
- Gently handle the *probe* when the *probe* is in contact with the cervix.
- During the measurement (continuous beeping) **do not push nor pull on the cervix**: the *probe handle* should not be too close to the *probe tip* nor too close to the *probe end*, but in the centre.

The Pregnolia System is composed of a reusable *control unit* (REF 100058) and a single-use *sterile probe* (REF 100026).

is not possible to find a suitable location near the ectopy where native tissue is present, large scar tissue – for which it is not possible to find a suitable location near the scar where native tissue is present.

Precautions

A repetition of the measurement is not harmful for the patient. However, repeated measurements can temporarily alter the properties of the cervical tissue, yielding different results. Therefore, the user should record the order in which the sequential measurement results were obtained, for future reference and/or comparison purposes. Special caution should be exercised in the presence of: female genital mutilation; *placenta praevia* without bleeding; active *herpes genitalis*; psychological reasons or issues. Special cautions should also be exercised if one of the following conditions is present outside the site of measurement (12 o'clock position): ectopy and cervical polyps, Nabothian cyst, squamous intraepithelial lesion, conisation / LEEP / LLETZ, cervical endometriosis.

Warnings

Do not measure directly on the cervical canal - Remove excessive mucus before the measurement - If an ectopy is visible at the 12 o'clock position, do not measure on the ectopy itself but find a location near the ectopy: either at the 12 o'clock position, avoiding the ectopy itself, or at positions 11 o'clock or 1 o'clock - Prior to each usage, inspect the integrity of the *probe sterile pouch*. Do not use the *probe* if the *probe sterile pouch* looks damaged or open, since sterility may be compromised - Do not dispose of the *probe sterile pouch* before the measurement is over as it contains necessary reference information in case of issues with the device - After each measurement, immediately dispose of the *probe* and the *probe sterile pouch* - Never reuse or re-sterilize a *probe* since this can lead to contamination or device abnormal functionality



Intended Use Statement

The Pregnolia System is used to provide information about the mechanical properties of the uterine cervix by assessing the tissue stiffness through a proxy parameter (the closing pressure, in mbar). Cervical stiffness can be assessed during routine examinations - along with other parameters, such as cervical length measured by ultrasound - in order to gather supportive data for diagnostics in the field of obstetrics and gynaecology, in particular about cervical remodelling. The Pregnolia System is intended to be used in addition to other standard examinations and does not substitute them.

Indications

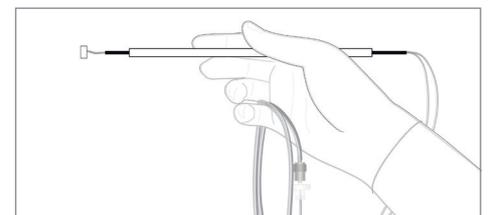
Assessment of tissue stiffness of the uterine cervix during pregnancy and gynaecological examinations.

Patient Population

The intended patient population are all pregnant and non-pregnant women, aged 18 years old or older, for which the assessment of the uterine cervix is indicated.

User Group

The Pregnolia System is intended to be used by health-care professionals with medical expertise in the fields of gynaecology or obstetrics, such as gynaecologists and midwives. The user must be familiar with speculum-based vaginal examinations. The user must have read the Instructions for Use. The system is not intended to be used by the patient.



- Never use a probe from a third-party supplier - Use gloves while handling the *probe* - Make sure the *probe* expiration date has not passed.

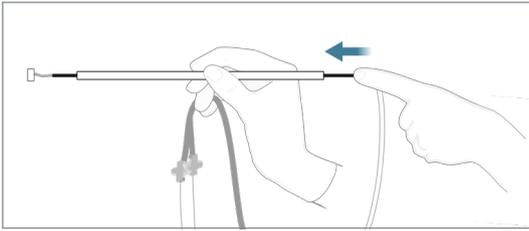
Probe connection instructions

- Open partially the *probe sterile pouch* from the side indicated by the label.
- Pull the *filters* and the *silicone tubes* out of the *pouch* while keeping the *probe* inside the *sterile pouch* to ensure it remains sterile.
- Attach the *filters* to the *connector cable*, while leaving the *probe* inside the sterile package.

Probe gripping

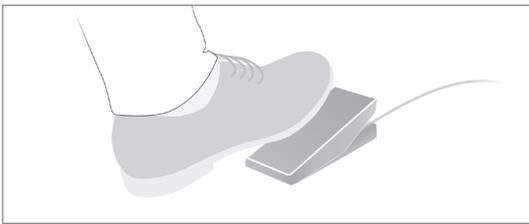
- Hold the *probe* as indicated in the **figure above**.
- **Important:** support the *filters* by taking the *connector cable* in your hand.
- Do not squeeze the *filters* and do not bend or kink the tubes.
- Hold the *probe* at the end closest to the *filters*, like a pen.

This guide is intended to supplement and NOT to replace the instructions for comprehensive usage of the Pregnolia System. Please refer to the Instructions for Use (P/N 100041) provided with the Pregnolia Control Unit (REF 100058) or online at www.pregnolia.com/instructions.

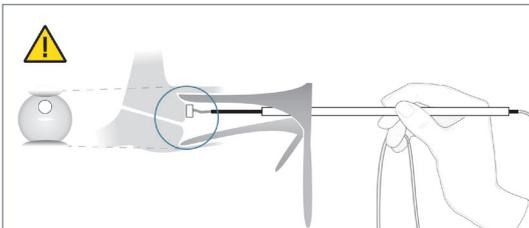


Push the *sliding tubes* completely inward.

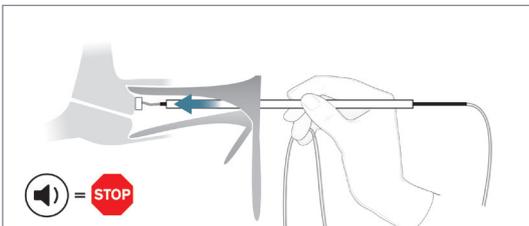
Remember to support the *filters* by taking the *connector cable* in the hand.



Press and release the *foot switch* to start the pump **before** inserting the *probe* into the vaginal canal.

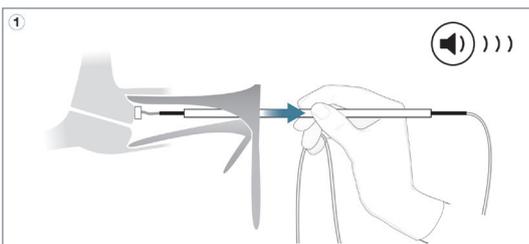


Gently place the *probe tip* through the speculum on the anterior lip of the cervix at the 12 o'clock position.

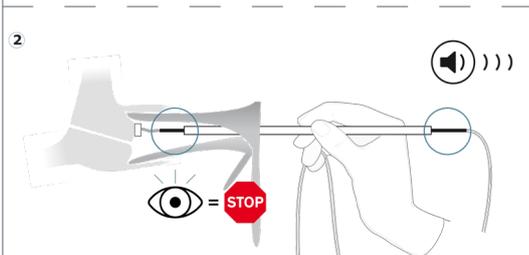


Gently push the *probe handle* inward until the first audio signal beep is heard (**be-beep**), then stop pushing the *probe*.

If the *tip* detaches, another sound is made (**boop**) and you will have to try again.

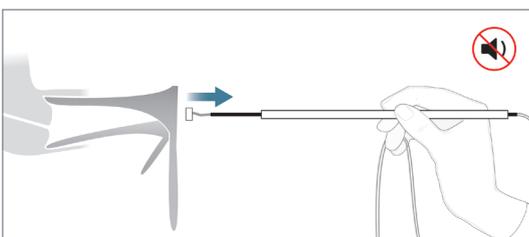


As soon as the tissue starts to be pulled into the *probe tip*, a continuous beeping is emitted (**beep-beep-...**). Position the *handle* approximately in the centre of the *probe* (see below):



The *handle* is centred when you see roughly the same length of free *probe sliding tube* in the front and in the back.

Hold this position until the measurement finishes (**be-be-beep**).



When the audio signal stops the measurement is completed. Gently remove the *probe* from the vaginal canal.